A-T

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,376	07/02/2001	Frank D. Hong	UTSC:645US/SLH	2755

7590 05/03/2004

FULBRIGHT & JAWORSKI L.L.P.
SUITE 2400
600 CONGRESS AVENUE
AUSTIN, TX 78701

EXAMINER	
YAEN, CHRISTOPHER H	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	Application No.	Applicant(s)	
	09/899,376	HONG ET AL.	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,7,9-15 and 86-89* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,3,7,9-15 and 86-89* is/are rejected.

7)☒ Claim(s) *3 and 9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

RE: Hong *et al*
Priority Date: 30 June 2000

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/19/2004 has been entered.

2. Claims 2,4-6,8, 16-85 are canceled without prejudice or disclaimer. Claims 1,3,7,9-15, and 86-89 are pending and examined on the merits.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

3. The rejection of claims 1,7,10-15, 86-89 under 35 USC 112, 1st paragraph as lacking written description is maintained for the reasons of record. Applicant argues that the amendment to the claims to recite a HN-1 peptide variant or HN-1 related peptide comprising SEQ ID No: 1 provides one of skill in the art with the proper written description of claimed variants or related peptides. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. The written description in this case has not set forth a disclosure that would properly entitle the applicant to claims that read on variants or related peptide of SEQ ID No: 1. The specification defines, "variants" as insertional variants, substitutional variants, and

conservative variants. However, the skilled artisan cannot decipher from the instant disclosure what these changes to the sequence of SEQ ID No: 1 would comprise. Furthermore, the genus encompassed by the term is extensive and the specification nor the claims ascribe any functional limitation to the said variants or related peptides so that one of skill in the art could readily screen for such variants. Furthermore, neither the specification nor the claims provide a specific number of mutations, substitutions, insertions, or deletions these variants or related peptides are intended to comprise. Although the specification and the art provide evidence that such changes are routinely performed, the specification nor the claims provide the artisan with any guidance as to what changes should be made. The general knowledge and level of skill in the art do not supplement the omitted disclosure, because specific not general guidance is what is needed. Therefore given the lack of guidance with regard to the broad genus of "variants" claimed and the lack of an identifiable characteristics or common attributes shared by the "variants", the sequence of SEQ ID No: 1 alone is insufficient to describe the genus. Thus the rejection of the claims as lacking written description is maintained.

New Arguments

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1, 3, 7, 9-15, and 86-88 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1, 3, 7, 9-15, and 86-88, as written, do not sufficiently distinguish over proteins as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified" as taught by page 6 of specification. See MPEP 2105.

Claim Rejections - 35 USC § 112, 1st paragraph

6. Claims 7 and 87 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case has only set forth a composition comprising an anti-cancer drug and a peptide of SEQ ID No: 1 and therefore the written description in this case is not commensurate in scope to claims that read on a composition comprising any and all drugs with a peptide of SEQ ID No: 1.

The written description of the term “drug” can be found in the specification as being “a medicament or medicine which is used for the therapeutic treatment of a

medical condition or disease" (see page 17). However, with the exception of anti-cancer drugs, no where beyond the recitation of this term does the specification elaborate on what other types of drugs are intended to be encompassed by this term. There are many other types of medicaments that fall within the scope of this term of which have not been adequately described in the specification, so as to entitle the applicant to the broad genus of "drugs" claimed. On pages 45-61, various exemplifications of drugs that are intended as representative "drugs" are outlined. All of the intended drugs are useful in the treatment of cancers or tumors. No other types of "drugs" have been taught that fall outside of the anti-cancer realm of "drugs." One of skill in the art would not reasonable correlate the function of cancer-type "drugs" with anti-inflammatory type "drugs", which might be useful for the treatment of allergies or general pain alleviation. The species of "drugs" disclosed cannot be reasonable representative of all types of "drugs" currently claimed.

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the

genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

Applicant does not appear to have reduced to practice the broad class of "drugs" claimed. Neither has Applicant provided a sufficient written description of any structure that may be correlated with the desired function of treating a medical condition or disease, aside from cancers. A "drug" encompasses *any* molecule with the functional activity treating a disease. Thus the genus of compounds encompassed by this term is extensive and the artisan would not be able to recognize that Applicant was in possession of the invention as now claimed.

Consequently, Applicant was not in possession of the instant claimed invention. See Regents of the University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Adequate written description of genetic material "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. Id.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001. Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 3/19/2004.

Conclusion

7. Claims 3 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
April 22, 2004

GARY NICKOL
PRIMARY EXAMINER